United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road
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Dr. John Sedbrook
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Re: Confirmation of the regulatory status of genome-edited CRISPR mutagenized *Thlaspi arvense* L. (pennycress) lines.

Dear Dr. Sedbrook,

Thank you for your letter dated July 8, 2019, inquiring whether the pennycress (*Thlaspi. Arvense)* product described in your letter is a regulated article under 7 CFR part 340. Your letter describes mutant pennycress lines developed using CRISPR genome editing technology and traditional breeding methods to confer the desired phenotype claimed as confidential business information (CBI).

The Plant Protection Act (PPA) of 2000 gives USDA the authority to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests or noxious weeds to protect the agriculture, environment, and economy of the United States.

USDA regulates the importation, interstate movement and environmental release (field testing) of certain genetically engineered (GE) organisms that are, or have the potential to be, plant pests. Regulations for GE organisms that are or have the potential to be plant pests, under the PPA, are codified at 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason To Believe Are Plant Pests." Under the provisions of these regulations, a GE organism is deemed a regulated article if it has been genetically engineered using a donor organism, recipient organism, or vector or vector agent that is listed in §340.2 and meets the definition of a plant pest, or that is an unclassified organism and/or an organism whose classification is unknown, or if the Administrator determines that the GE organism is a plant pest or has reason to believe it is a plant pest.

In your July 8, 2019 letter, you describe the production process of your genome-edited CRISPR mutant pennycress lines, the intended phenotype and supporting evidence. These genome-edited pennycress lines were obtained using a CRISPR DNA construct designed for targeted genome editing of one gene, using disarmed *Agrobacterium tumefaciens* and traditional breeding techniques (segregation of the introduced genetic material). The expression cassette introduced into the wild-type lines contained DNA elements necessary for gene editing and antibiotic resistance, and included DNA from plant pests. Three independent plant lines were found to have mutations at the expected location. Your inquiry stated that these mutations resulted from the plant's error-prone endogenous DNA repair mechanism. Mutant lines with no traces of the CRISPR DNA construct were generated by back-crossing the originally transformed lines to wild-type

plants. The segregation of inserted transgenic material was possible since the CRISPR construct had been inserted into a chromosomal location unlinked to the targeted gene. The progeny lines were screened for lack of antibiotic resistance and by PCR analysis to confirm the absence of intentionally inserted DNA sequences.

Based on the information provided in your July 8, 2019 letter, USDA has concluded that your genome-edited mutant pennycress lines are not themselves plant pests. USDA has accepted your attestation that these genome-edited pennycress lines do not contain any deliberately inserted DNA sequences. Therefore, consistent with previous responses to similar letters of inquiry, USDA does not consider the genome-edited pennycress lines as described in your July 8, 2019 letter to be regulated pursuant to 7 CFR part 340. Additionally, pennycress is not listed as a Federal noxious weed pursuant to 7 CFR part 360, and USDA has no reason to believe that the intended phenotypes in your two pennycress lines would increase the weediness of pennycress.

Please be advised that the importation of seeds or plants from your genome-edited pennycress lines, like all other pennycress, will be subject to Plant Protection and Quarantine (PPQ), permit and/or quarantine requirements. For further information, should you plan to import these pennycress seeds or plants, you may contact the PPQ general number for such inquiries at (877) 770-5990.

Please be advised that your pennycress, while not regulated by APHIS under 7 CFR part 340 may still be subject to other regulatory authorities such as the U.S. Environmental Protection Agency (EPA) or the U.S. Food and Drug Administration (FDA). To inquire about the regulatory status of your product with the EPA, please contact Alan Reynolds at 703-605-0515. To inquire about the regulatory status of your product with the FDA, please contact Robert Merker at 240-402-1226.

Should you become aware at any time of any issues that may affect the Agency's conclusion regarding this inquiry, you must immediately notify the Agency in writing of the nature of the issue. We hope that you appreciate our commitment to plant health and support for the responsible stewardship for the introduction of GE plants.

Sincerely,

Bernadette Juarez
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

1/29/2020
Date